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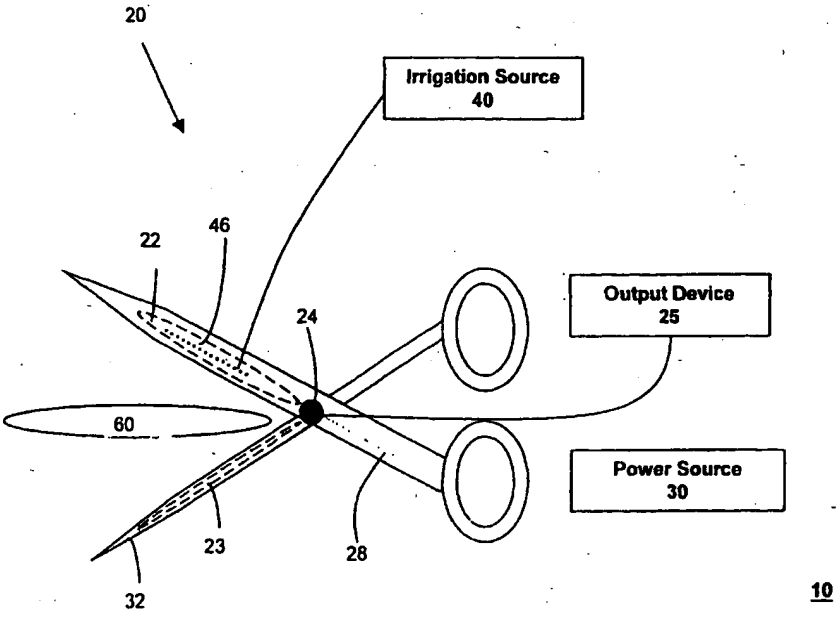
(54) Title: VIBRATION SENSITIVE ABLATION APPARATUS AND METHOD



(57) Abstract: An ablation apparatus including a maneuvering mechanism, a conductive element attached to the apparatus, a sensor attached to the apparatus and an output device in communication with the sensor is provided. The sensor senses vibration during the ablation procedure and sends a signal to the output device to reduce power to the conductive element.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

VIBRATION SENSITIVE ABLATION APPARATUS AND METHOD

FIELD OF THE INVENTION

This invention relates to ablation devices that are used to create lesions in tissue. More particularly, this invention relates to ablation devices that are capable of monitoring the level of energy being used to ablate the tissue and of preventing the energy from creating tissue-damaging events such as a "steam pop."

BACKGROUND OF THE INVENTION

Ablation of organic tissue, such as heart, lung or liver tissue, is a technique used in several surgical procedures, for both diagnosis and therapy. In one instance, electrodes at the tips of an electrophysiology ablation device allow the physician to measure electrical signals along the surface of the heart (mapping). In another instance, the physician may also ablate certain tissues using energy (such as radiofrequency energy) conducted to one or more ablation electrodes. Higher levels of energy are used to cut and remove tissue (electrosurgery). Lower levels of energy are used to cause cell damage but leave the structure intact so that electrical pathways are blocked within the tissue.

A variety of devices may be used to ablate tissue. Typically, such devices include a conductive tip, which serves as one electrode in an electrical circuit. The electrical circuit is completed via a grounding electrode that may also be on the device or may be coupled to the patient. By controlling the level of energy transmitted to the ablation electrode, the user is able to control the amount of heat generated for the purposes described above. The ablation site may also be irrigated to cool the electrode and create greater lesion depth.

In order to control the level of energy transmitted, the user must monitor the level of energy being transmitted from the electrode. Typical systems for monitoring ablation energy rely on temperature. A thermocouple element is located within the ablation device, generally near the electrode. This temperature-measuring element effectively measures the temperature of the electrode rather than the tissue being ablated. Particularly when the

site is being irrigated with a conductive fluid, the temperature of the tissue may differ to some degree from the temperature of the ablation device.

Additionally, water (from within and around the tissue) is present at the ablation site. The heat required to raise the temperature of liquid water by 1°C is 1.0 kcal/g. However, due to the unique chemical structure of the water molecule, additional heat is required for water to change phase from the liquid to gaseous phase. If the temperature at the ablation site exceeds 100°C, the water will change phase, boil and may result in an audible "steam pop" within the tissue. This pop may damage and even rupture the tissue. Irrigation cooling of the site shifts the location of the "steam pop" even deeper within the tissue, resulting in even greater damage than a superficial pop.

It has been observed that before a "steam pop", there is a mechanical vibration within the tissue (suspected to be caused by the phase transition of water, which may create microbubbles within the tissue). This vibration transfers to the ablation device. A sensitive enough instrument and a sensitive enough user may perceive this vibration in time to halt ablation, for example, by turning off the energy being delivered to the ablation device. However, due to such reasons as slow human reaction, vibration damping from the device or vibration damping from the tissue, the user is often not able to halt ablation in time to prevent damage.

Thus a means for sensing this vibration in time to halt ablation would be desirable. In addition, a means of automatically halting ablation or modifying the amount of ablation energy being transmitted when this vibration occurs would also be desirable. Moreover, a means of alerting a user to halt or modify ablation would also be desirable.

SUMMARY OF THE INVENTION

One aspect of the invention provides an ablation apparatus. The apparatus may include a maneuvering mechanism, a conductive element attached to the mechanism, a sensor attached to the mechanism and an output device attached to the sensor. The sensor may sense vibration during an ablation procedure, including the excitation of water molecules within tissue being ablated and the vibration of the conductive element. Upon sensing this vibration, the sensor may send a signal to the output device to respond to the

signal by reducing or halting power to the conductive element. The apparatus may also give a visual or audio signal to a user to control the power. The sensor may also control a fluid supply in a similar manner. The sensor may be integrated with the conductive element. The sensor may be, for example, a microphone or a piezoelectric crystal. The maneuvering mechanism may be, for example, a hemostat-like handle or a catheter.

Another aspect of the invention provides for an ablation apparatus including a maneuvering mechanism. The maneuvering mechanism may include a conductive element, a sensor adjacent the conductive element and an output device in communication with the conductive element. The sensor may sense vibration caused by an ablation procedure and send a signal to the output device to reduce or turn off power to the conductive element. The output device may also signal the user to control the power to the conductive element. The sensor may be a piezoelectric crystal, a piezoelectric polymer or a mechanical sensor. The sensor may be integrated with the conductive element. The maneuvering mechanism may be, for example, a hemostat-like handle or a catheter.

Another aspect of the invention provides a method of ablating organic tissue. A conductive element may be positioned adjacent the organic tissue. Power may be supplied to the element to ablate the tissue. A sensor maybe be positioned adjacent the conductive element to sense the vibration of the organic tissue. When the vibration reaches a given value, power to the conductive element may be reduced or turned off. The sensor may also send a signal via an output device to reduce or turn off power. A related method may be used to turn off or reduce fluid being supplied to the tissue. The sensor may be a piezoelectric crystal, a piezoelectric polymer. The sensor may be integrated with the conductive element.

The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view of a system for ablating tissue in accordance with the present invention;

FIG. 2 is a schematic view of one embodiment of an ablation apparatus in accordance with the present invention; and

FIG. 3 is a side view of another embodiment of an ablation apparatus in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

FIG. 1 shows a system **10** for ablating tissue in accordance with the present invention. Typically the tissue to be ablated may be located within the body cavity, such as the endocardial or epicardial tissue of the heart. Other body organ tissue, such as the liver or lung, may also be ablated using the present invention. System **10** may include an ablation apparatus **20** that comprises a conductive electrode **22**, a sensor **24** connected to an output device **25** and a connection **28** to a source of ablation energy. System **10** may further include a power source **30** that provides ablation energy. System **10** may also include an indifferent (non-ablating) electrode **23** which may serve as the return plate for energy transmitted through electrode **22**. Electrode **23** may be placed elsewhere on the patient's body than the ablation site. For example, electrode **23** may be placed on the patient's back or thigh. System **10** may further include an irrigation source **40** that provides irrigation fluid to the ablation site. Ablation apparatus **20** or electrode **22** of ablation apparatus **20** may also include fluid openings **46** through which irrigation fluid may flow to the site.

In use, a user may manipulate ablation apparatus **20** so that electrode **22** contacts the surface of the tissue to be ablated. Power source **30** provides energy to the apparatus **20** via connection **28**. This connection may be any suitable connection for conducting energy from power source **30** to apparatus **20**. Power source **30** may be any suitable power source such as, for example, standard electrical power available in the operating room. Once power source **30** is turned on, the user may use apparatus **20** to ablate the tissue with energy from source **30**.

As ablation occurs, it is sometimes desirable to irrigate the ablation site with irrigation fluid, which may be, for example, any suitable fluid such as saline or another conductive fluid. The irrigating fluid may cool the electrode **22** of ablation apparatus **20** and may allow for greater lesion depth. Furthermore, continuous fluid flow may keep the ablation device surface temperature below the threshold for blood coagulation, which may clog the device. Use of irrigating fluid may therefore reduce the need to remove a clogged ablation device for cleaning or replacement. The presence of an ionic fluid layer between electrode **22** and the tissue to be ablated may also ensure that an ionic fluid layer conforming to the tissue contours is created. In one preferred embodiment, saline solution is used. Alternatively, other energy-conducting liquids, such as Ringer's solution, ionic contrast, or even blood, may be used. Diagnostic or therapeutic agents, such as lidocaine, CA^{++} blockers, ionic contrast, or gene therapy agents may also be delivered before, with or after the delivery of the irrigating fluid. Irrigation source **40** may be any suitable source of irrigation fluid such as, for example, a standard irrigation pump (not shown). This pump may also be connected to power source **30** or may have its own source of power. Preferably, apparatus **20** may also include means for delivering irrigation to the ablation site from irrigation source **40**. Such means may be, for example, fluid openings **46**.

FIG. 2 shows a perspective view of ablation apparatus **20**. Ablation apparatus **20** may be any suitable ablation tool such as, for example, a catheter, an electrocautery device, an electrosurgical device, a suction-assisted ablation tool, an ablation pod, an ablation paddle, an ablation hemostat or an ablation wire. Ablation apparatus **20** or its components are preferably made of a biocompatible material such as stainless steel, biocompatible epoxy or biocompatible plastic. Preferably a biocompatible material prompts little allergenic response from the patient's body and is resistant to corrosion from being placed within the patient's body. Furthermore, the biocompatible material preferably does not cause any additional stress to the patient's body, for example, it does not scrape detrimentally against any elements within the surgical cavity.

Preferably, ablation apparatus **20** may be permanently or removably attached to or incorporate a maneuvering apparatus for manipulating apparatus **20** onto a tissue surface. Such an apparatus may be, for example, hemostat handles **12** as shown in **FIGS. 1** and **2**. Ablation apparatus **20** may be located on one or more of the hemostat jaws **32**.

Alternatively ablation apparatus **20** may be mounted on a pen-like maneuvering apparatus. Ablation apparatus **20** may also include an appropriate catheter handle, such as, for example, the handle of a transvenous catheter. Alternatively any appropriate flexible or rigid handle may be used as a maneuvering apparatus.

Apparatus **20** also preferably includes a connection **28** suitable for conducting energy to apparatus **20**, particularly to conductive element **22** from a power source.

The conductive element **22** of ablation apparatus **20** is preferably an electrode **22**. This electrode **22** may be positioned in any suitable place on apparatus **20**. Preferably electrode **22** is placed near an end of the apparatus **20**, away from the user, to be more easily manipulated against the tissue **60** to be ablated. As shown in the embodiment of **FIG. 2**, apparatus **20** may incorporate an anode electrode **22** and a cathode electrode **23** in a bipolar circuit. The two electrodes **22, 23** may be arranged on the jaws of a hemostat-like tool. Electrodes **22, 23** may each be, for example, weeping electrodes, double wound coil electrodes, electrode needles or any other suitable electrode.

As **FIG. 2** shows, a sensor **24** may be permanently or removably incorporated into apparatus **20**. This sensor **24** may sense the vibration in tissue that occurs prior to a "steam pop" as described above. Sensor **24** may sense this vibration in time to alert the user to halt ablation. Preferably, sensor **24** may sense the vibration of the tissue. Alternatively, the vibration of the tissue may be transferred to the apparatus **20** and sensor **24** may sense the vibration of the device. In the embodiment of **FIG. 2**, this sensor **24** may be incorporated into the apparatus **20**, preferably near one of the electrodes **22, 23**. The vibration signal from tissue **60** becomes more dampened the farther away from the ablation site sensor **24** is placed. Thus, sensor **24** is preferably located as close as possible to the ablation site. For example, as shown in **FIG. 2**, sensor **24** may be located near the tip of one or more jaws of a hemostat-like tool. Alternatively, as shown in **FIG. 3**, sensor **24** may be located near the tip of a catheter-type tool, such as an intravenous catheter.

Apparatus **20** may include a separate sensor for each of electrodes **22, 23**, as seen in **FIG. 2**. Apparatus **20** may also include one sensor that may serve its function for both electrode **22** and electrode **23**, as seen in **FIG. 1**. Apparatus **20** may also have a series of sensors along the entire length of the device, particularly if the device is longer, such as a

catheter. Placement of a series of sensors on apparatus **20** may ensure that at least one sensor will be located near the ablation site no matter how long the device.

Sensor **24** is preferably a piezoelectric crystal highly sensitive to vibration. Sensor **24** may also be a piezoelectric polymer. The signal given out by such a piezoelectric crystal or polymer is proportional to the amount of vibration it senses. Thus, the intensity of the signal transmitted by sensor **24** corresponds to the intensity of the vibration. A piezoelectric element is typically attached to or placed near a vibrating structure (such as, for example, vibrating tissue). As the vibrating structure moves relative to its surrounding space, its mass exerts an inertial force on the piezoelectric element. The exerted force produces a proportional electric charge on the piezoelectric element.

Alternatively, sensor **24** may be, for example, a microphone. Sensor **24** may also be any suitable mechanical sensor of appropriate dimensions for incorporation into an ablation apparatus **20**.

The signal from sensor **24** may preferably be amplified by a suitable amplifier (not shown) before reaching output device **25**. The amplifier may be incorporated into output device **25**. Alternatively the amplifier may be incorporated into ablation apparatus **20**. Alternatively, the amplifier may be a separate device.

Output device **25** may receive and preferably interpret the signal from sensor **24**. For example, output device **25** may be capable of filtering out signals that differ from the signal resulting from a "steam pop" vibration. For example, the signal from the vibration of someone tapping on the operating table may be differentiated from the signal resulting from a "steam pop" vibration. Such filtering of vibration signals may be programmed in software using appropriate algorithms. Alternatively, the filtering of vibration signals may be designed into hardware electronics.

Output device **25** may be a device separate from power source **30** and irrigation source **40**. Output device **25** may also be incorporated into power source **30**, irrigation source **40**, or ablation apparatus **20**.

In one embodiment, sensor **24** is a piezoelectric element and may generate a voltage as its signal. Sensor **24** may generate this voltage without any additional power. If necessary, for example, for another type of sensor, connection **28** described above may

provide power to sensor **24** from power source **30**. Sensor **24** may also have its own connection and/or its own power source for additional power if necessary.

In use, while the user is ablating the tissue **60**, the water at the ablation site may begin to simmer and vibrate accordingly. Simmering and vibration may occur if the site is irrigated or not. Water at the site may be water from within or around the tissue. If this simmering continues unabated, a "steam pop" as described above, will occur. Such a simmering vibration may be sensed by sensor **24** which will produce a signal to output device **25**. For example, output device **25** may preferably be a switch, which, at a signal from sensor **24**, turns off power from source **30**. Such an automatic feedback system for interrupting ablation energy may prevent the "steam pop." If the ablation site is being irrigated from irrigation source **40**, the switch may also turn off fluid flow from irrigation source **40**.

Alternatively, output device **25** may control the power level from the power source **30**. A signal of a first intensity from sensor **24** may indicate that the power level from power source **30** should be lowered; a signal of a different intensity may indicate that the power source **30** should be turned off. Preferably, device **25** may be configured so that it may automatically raise or lower the power from source **30** appropriately. Alternatively, the control of power source **30** based on output from output device **25** may be manual.

Output device **25** may also be a visual display that indicates to the user that ablation energy should be halted. Such a display may be, for example, an indicator on a monitor. In one example, the monitor may display the voltage corresponding to the signal emitted from sensor **24**. This signal corresponds in turn to the intensity of the vibration at the tissue site. Therefore a voltage level of 2 would indicate that the tissue was vibrating more intensely than when the voltage level was 1. In this example, a user would monitor the voltage level and, if it exceeded a certain value, would turn off the power source **30**.

Alternatively, the display of device **25** may be located on the apparatus **20** itself, as shown in **FIG. 2**. In this embodiment, an indicator **36**, such as an LED light is permanently or removably incorporated into apparatus **20**. The indicator **36** may receive a signal from sensor **24** indicating that the tissue vibration had reached a level that might indicate an impending "steam pop." In response, indicator **36** may turn on, change color, grow brighter or change in any suitable manner to indicate that the flow of power from

source 30 should be modified or halted. The indicator may also be located on power source 30 or may be located on another location visible to the user.

Alternatively, output device 25 may be an audio device that indicates to the user that ablation energy should be halted. Such an audio device may be, for example, a speaker that broadcasts a sound (for example, a beep) that increases in intensity as the intensity of the vibration sensed by sensor 24 increases. The user may turn down or turn off power source 30 when the sound emitted reaches a given volume. In another embodiment, the audio device may also give an audible signal (such as the message "turn off power source") when the intensity of the vibration sensed by sensor 24 reaches a certain level. Such an audio device may be located on the ablation apparatus 20 itself, on power source 30, or on irrigation source 40. The audio device may also be a separate device.

FIG. 3 shows another embodiment of ablation apparatus 320 in which cathode electrode 323 may be placed elsewhere than on apparatus 320. In such a monopolar arrangement, for example, anode electrode 322 is positioned on the tissue 360 to be ablated. Meanwhile, cathode electrode 323 may be placed on the patient's back, thigh or elsewhere on the patient. Apparatus 320 also includes a handle 326 and a connection 328 to power source 330.

In the embodiment of FIG. 3, apparatus 320 may incorporate fluid openings 346 into the electrode 322. These fluid outlets may be connected to a conduit 344 that conducts irrigation fluid from irrigation source 340.

FIG. 3 shows that apparatus 320 may integrate sensor 324 into electrode 322. For example, electrode 322 may be located near a distal tip of an intravenous catheter and sensor 324 may be integrated into electrode 322 at the tip. This sensor 324 may act in the manner described above to sense the vibration of an impending "steam pop." Sensor 324 may then produce a signal to output device 325. Output device 325 is preferably a switch that, at the signal from sensor 324, turns power source 330 off. Such an automatic feedback system for interrupting ablation energy may prevent the "steam pop." It is contemplated that the switch may also be able to turn irrigation source 340 off. In FIG. 3, output device 325 is shown as a separate device connected to power source 330. Output

device **325** may also be located on power source **330** or may be located on ablation device **320**.

Alternatively, output device **325** may produce a visual or audio signal such as those described above to indicate that ablation should be halted.

It is contemplated that the ablation device of the present invention may incorporate additional devices, such as, for example, thermocouple elements to measure the temperature of the device or suction devices for to better anchor the device to the tissue.

It is further contemplated that the vibration sensitive ablation device of the present invention may be used in a variety of ablation systems such as those available from Medtronic, Inc., Minneapolis, Minnesota.

It should be appreciated that the embodiments described above are to be considered in all respects only illustrative and not restrictive. The scope of the invention is indicated by the following claims rather than by the foregoing description. All changes that come within the meaning and range of equivalents are to be embraced within their scope.

I CLAIM:

1. An ablation apparatus comprising:

a maneuvering mechanism;

a conductive element attached to the maneuvering mechanism;

a sensor attached to the maneuvering mechanism and operatively adapted to sense vibration during an ablation procedure; and

an output device in communication with the sensor and operatively adapted to respond to a signal from the sensor, wherein the signal corresponds to a sensed vibration.

2. The apparatus of claim 1 wherein the sensed vibration comprises the excitation of water molecules.

3. The apparatus of claim 1 wherein the sensed vibration comprises vibration of the conductive element.

4. The apparatus of claim 3 wherein the vibration of the conductive element corresponds to a vibration within the tissue.

5. The apparatus of claim 1 wherein the output device comprises a switch operatively adapted to turn off power to the conductive element when the vibration has reached a given value.

6. The apparatus of claim 1 wherein the output device is adapted to reduce power to the conductive element when the vibration exceeds a predetermined value.

7. The apparatus of claim 1 further comprising:

a power source in communication with the conductive element, wherein the output device gives a visual signal to a user to control the power source.

8. The apparatus of claim 1 further comprising:

a power source in communication with the conductive element, wherein the output device gives an audible signal to a user to control the power source.

9. The apparatus of claim 1 wherein the sensor is integrated with the conductive element.

10. The apparatus of claim 1 wherein the sensor comprises a microphone.

11. The apparatus of claim 1 wherein the sensor comprises a piezoelectric crystal.

12. The apparatus of claim 1 further comprising:

a fluid supply in communication with the apparatus, wherein the output device includes a switch operatively adapted to turn off the supply when the vibration has reached a given value.

13. The apparatus of claim 1 further comprising:

a fluid supply in communication with the apparatus, wherein the output device gives an indication to the user to control the fluid supply.

14. The apparatus of claim 1 wherein the maneuvering mechanism is a hemostat-like tool.

15. The apparatus of claim 1 wherein the maneuvering mechanism is a catheter.

16. An apparatus for ablating organic tissue, comprising:

a maneuvering mechanism;

a conductive element disposed adjacent a face of the maneuvering mechanism;

a sensor adjacent the conductive element; and

an output device in communication with the conductive element, wherein the sensor is operatively adapted to sense vibration caused by an ablation procedure and send a signal to the output device to reduce power to the conductive element.

17. The apparatus of claim 16 wherein the sensor is a piezoelectric crystal.

18. The apparatus of claim 16 wherein the sensor is a piezoelectric polymer.

19. The apparatus of claim 16 wherein the sensor is a mechanical sensor.

20. The apparatus of claim 16 wherein the sensor is integrated with the conductive element.

21. The apparatus of claim 16 wherein the output device is a switch operatively adapted to turn off a power source when the vibration has reached a given value.

22. The apparatus of claim 16 wherein the output device gives a signal to a user to control a power source operatively connected to the conductive element.

23. The apparatus of claim 16 wherein the maneuvering mechanism is a hemostat-like tool.

24. The apparatus of claim 16 wherein the maneuvering mechanism is a catheter.

25. A method of ablating organic tissue, comprising:

positioning a conductive element adjacent the organic tissue;

supplying power to the conductive element;

sensing with a sensor positioned adjacent the conductive element the vibration of the organic tissue; and

reducing power to the conductive element when the vibration reaches a given value.

26. The method of claim 25, further comprising:
halting the power when the vibration reaches a given value.

27. The method of claim 25, further comprising:
supplying fluid from a fluid supply to the tissue; and
halting the fluid supply when the vibration reaches a given value.

28. The method of claim 25 further comprising:
sending a signal from the sensor to a switch to reduce the power.

29. The method of claim 25, further comprising:
providing output from an output device when the vibration reaches a given value.

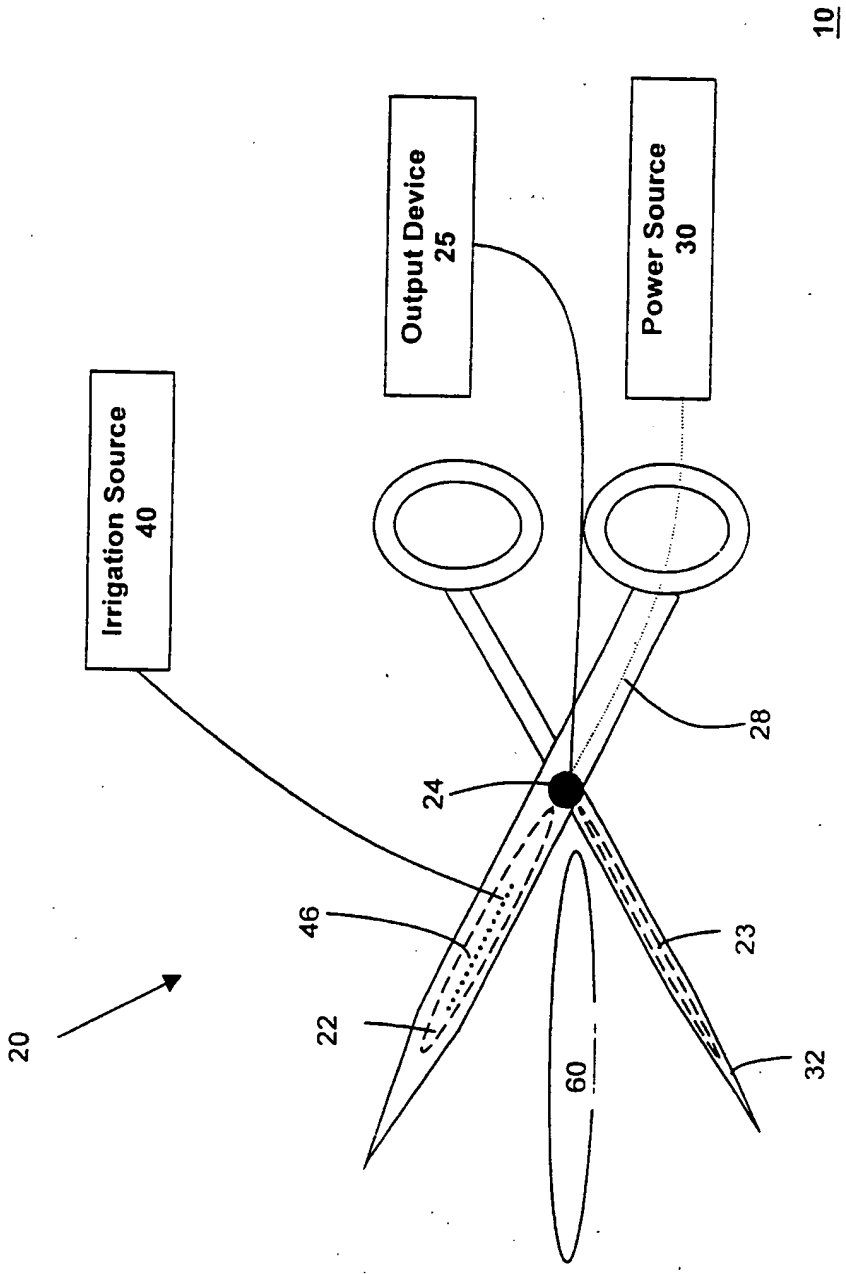
30. The method of claim 29 further comprising:
sending a signal from the sensor to the output device; and
sending an indicator signal from the output device.

31. The method of claim 25 wherein the sensor is a piezoelectric crystal.

32. The method of claim 25 wherein the sensor is a piezoelectric polymer.

33. The method of claim 25 wherein the sensor is integrated with the conductive element.

FIG. 1


10
Irrigation Source
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Output Device
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Power Source
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FIG. 2

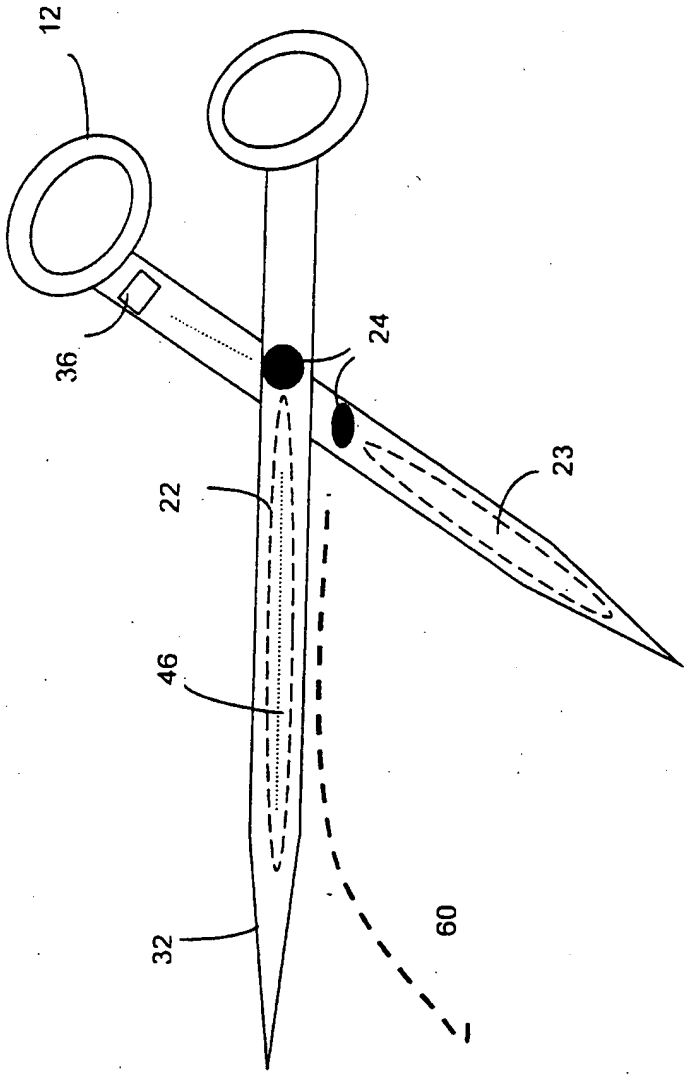
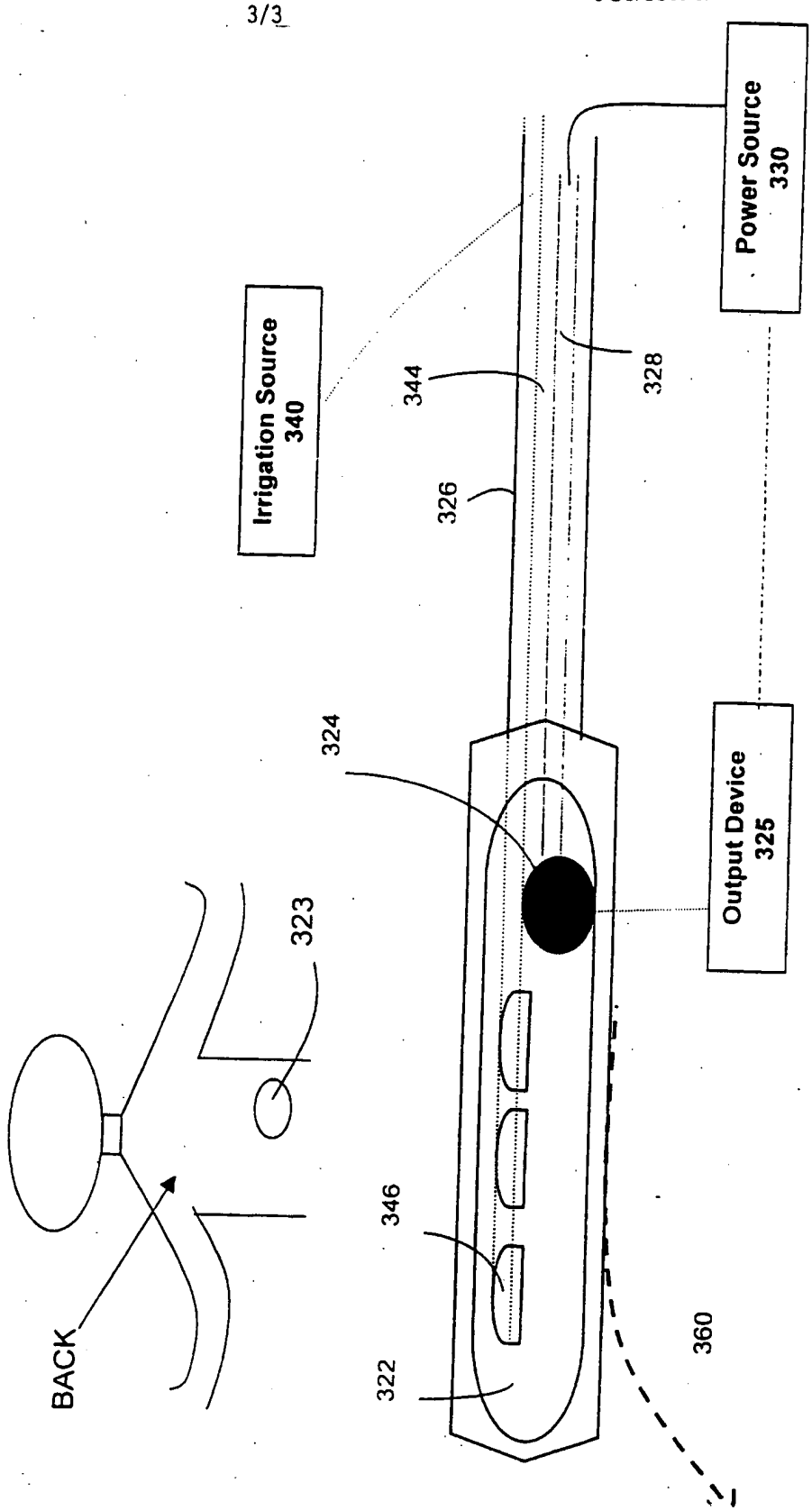


FIG. 3


Irrigation Source
340
Power Source
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Output Device
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BACK

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/12626

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 188 111 A (YATES DAVID C ET AL) 23 February 1993 (1993-02-23) column 4, line 42 - line 45; figure 1 column 7, line 66 -column 8, line 27; figure 4	1,5,6,9, 15,16
A	US 5 334 193 A (NARDELLA PAUL C) 2 August 1994 (1994-08-02) abstract; figures 4,5	12,15
A	GB 2 070 935 A (KENDALL & CO) 16 September 1981 (1981-09-16) page 2, line 6 - line 9; figure 2 page 2, line 52 - line 58	1,10,15, 16
A	US 5 864 066 A (KIM TAE-HO) 26 January 1999 (1999-01-26) abstract	1,11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 July 2001	20/07/2001

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